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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,735	09/09/2003	Antoni Kozlowski	SHE0064.00	3908
21968 7590 01/25/2008 NEKTAR THERAPEUTICS 201 INDUSTRIAL ROAD SAN CARLOS, CA 94070			EXAMINER FUBARA, BLESSING M	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 01/25/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/659,735

Applicant(s)

KOZLOWSKI, ANTONI

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-51 and 53-85 is/are pending in the application.
- 4a) Of the above claim(s) 1-27,31-37,45,50,51 and 55-85 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-30,38-44,46-49,53 and 54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/11/07 and 01/08/08</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Examiner acknowledges receipt of IDS, amendment and remarks, all filed 10/11/07 and supplemental IDS filed 01/08/2008. Claims 28,, 29. 53 and 54 are amended. Claim 52 is canceled. Claims 1-51 and 53-85 are pending. Claims 1-27, 31-37, 45, 50, 51 and 55-85 are withdrawn from consideration. Claims 28-30, 38-44, 46-49, 53 and 54 are under examination

*The examiner thanks attorney Mark A. Wilson for providing a list of the references cited in the EP "Examination Report" filed 10/11/2007.*

#### ***Response to Arguments***

**Previous rejections that are not reiterated herein are withdrawn.**

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 28-30, 38-42, 46, 47, 49, 52 and 53 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bergstrom et al. (WO 99/32424).

Bergstrom discloses ortho ester based surfactants where ortho ester linkages (page 1, lines 3-8) connect the hydrophobic and hydrophilic parts; the ortho ester portion is represented by formula (II) (page 4, lines 13-16 representing the moiety of claims 52, 53, and 28. The hydrophilic part of the molecule is derived from polyethylene glycols that are end-capped having

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molecular weight of between 100 and 2000 (page 5, lines 9-14) meeting the "Poly---" of the polymer of claims 28, 38-41, 46, 47 and 48. Therefore, Bergstrom meets the claims.

***Response to Arguments***

3. Applicant's arguments filed 10/11/07 have been fully considered but they are not persuasive.

Applicant argues that Bergstrom does not teach the orthoester of claim 28 because Bergstrom defines R as C<sub>1-7</sub> atoms while correspondingly, the POLY in the claims is a water soluble polymer.

Response:

While Bergstrom defines R as C<sub>1-7</sub> atoms, Bergstrom also describes reaction of triethyl orthoformate with methyl capped PEG which would produce the orthoester (Examples 1-6). Bergstrom also teaches that the orthoester comprises hydrophobic and hydrophilic components, with the hydrophilic and hydrophobic components each individually connected by ortho ester bond to the molecule (page 4, lines 1-3, 7-10); Bergstrom specifically identifies the hydrophilic part as polyethylene glycols (page 5, lines 9-12).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claims 28, 42-44 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergstrom et al. (WO 99/32424) in view of Hunter et al. (US 5763538) and Baker (US 5,634,971).

Bergstrom is described above. Regarding claim 54, which is directed to cyclic form of the ortho ester moiety, it is noted that one ortho ester can be used in place of the other and expect both polymers, one with the moiety of Bergstrom and the other having another moiety such as the cyclic ortho ester, to be drug delivery vehicles and other uses. The polyethylene glycol portion of the polymer of Bergstrom is end-capped with alkyl groups such as methyl and ethyl. Bergstrom does not cap the polyethylene glycol with alkoxy groups as is recited in claims 42-44. However, it is known in the art that alkyl, such as methyl and alkoxy such as ethoxy and methoxy are used to end-cap polyethylene glycol and the teachings of Hunter and Baker; Hunter teaches polyethylene glycol that is end-capped with methoxy or ethoxy (column 2, lines 44 and 45; claims 5 and 7); Baker teaches end-capping polyethylene glycol with methyl groups. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the polymer of Bergstrom having methyl end-capped polyethylene glycol. One having ordinary skill in the art would have used alkoxy-end-capped polyethylene glycol and expect the effects of both polymers to be unaltered in the delivery of active agents.

#### *Response to Arguments*

6. Applicant's arguments filed 10/11/07 have been fully considered but they are not persuasive.

7. Applicant argues that the Hunter and Baker references do not remedy the deficiencies of Bergstrom because neither Hunter nor Baker teaches or suggests ortho ester functional group or

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suggests the location of water soluble polymer segment at a particular location and that the claimed invention is not a mere combination of prior art elements.

Response:

The structure of the ortho ester is provided by Bergstrom and Hunter and Baker are relied upon for teaching polyethylene glycol can be end capped with ethoxy and methoxy (Hunter) and methyl (Baker).

No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


9. This application contains claims 1-27, 31-37, 45, 50, 51 and 55-85 drawn to an invention nonelected with traverse in the reply filed on 10/19/2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Blessing Fubara  
Patent Examiner  
Tech. Center 1600

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER